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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

CHAYA GROSSBAUM and
MENACHEM GROSSBAUM, her
spouse, individually and as *guardians
ad litem* of the infant ROSIE
GROSSBAUM,

Plaintiffs,

-VS-

GENESIS GENETICS INSTITUTE,
LLC, of the State of Michigan, MARK
R. HUGHES, NEW YORK
UNIVERSITY SCHOOL OF
MEDICINE and NEW YORK
UNIVERSITY HOSPITALS
CENTER, both corporations in the
State of New York, ABC CORPS. 1-
10, JOHN DOES 1-10,

Defendants.

CIVIL ACTION NO.
07-CV-1359 (GEB)(ES)

**DEFENDANTS GENESIS
GENETICS INSTITUTE, LLC AND
MARK R. HUGHES'S STATEMENT
OF UNDISPUTED MATERIAL
FACTS PURSUANT TO LOCAL
CIVIL RULE 56.1**

Pursuant to Local Civil Rule 56.1, Defendants Genesis Genetics Institute, LLC (“Genesis Genetics”) and Mark R. Hughes (“Hughes”) (collectively, “Genesis”) respectfully submit the following Statement Of Undisputed Material Facts Pursuant To Local Civil Rule 56.1 in support of their motion for summary judgment submitted simultaneously herewith.

The following are material facts as to which Genesis contends that there are no genuine issues to be tried:

I. PLAINTIFFS’ INTERACTIONS WITH GENESIS AND NYU

1. As high school students, Plaintiffs Chaya and Menachem Grossbaum, who both attended Jewish day schools, were tested by a community organization, Dor Yeshorim, to see if they were carriers of a number of genetic mutations that are more prevalent than average within the Jewish community. (Ex. 9¹ (Deposition of C. Grossbaum, Vol. I, 12/17/08) at 39:18 - 43:8.) When Chaya and Menachem Grossbaum were considering getting engaged, they contacted the organization that conducted the screening to see whether they were “compatible or not.” (*Id.* at 40:15.) At that time, they learned that they were both carriers of cystic fibrosis (“CF”). (*Id.* at 40:15 - 17.)

2. When both parents are carriers of CF mutations, there is a 25% chance that any child they conceive together will have CF. (Ex. 8 (Deposition of Menachem Grossbaum, 3/12/09) at 18:15 - 25.)

3. Upon learning of their carrier status, the Grossbaums consulted a number of rabbis for advice on (1) whether to get married, and, if they did choose

¹ Citations to Ex. __ are citations to the exhibits to the Declaration Of Sarah Blaine, Esq. In Support Of Genesis Genetics Institute, LLC And Mark R. Hughes’s Motions For Summary Judgment And To Disqualify Plaintiffs’ Liability Experts, submitted simultaneously herewith.

to get married, (2) what reproductive options were available to them under Jewish law. (Ex. 9 at 45:12 - 50:23, 64:10 - 66:12, 179:18 - 180:4; Ex. 8 at 12:1 - 15:1.)

4. Because of their religious convictions, Chaya and Menachem Grossbaum are both opposed to abortion, and their deposition testimony reflects that, in accordance with their understanding of Jewish law, they would not opt to abort if they learned that Chaya Grossbaum was carrying a child with CF. (Ex. 9 at 66:5 - 12; Ex. 8 at 18:5 - 14.) They reached this conclusion based on advice they received from Rabbi Tendler, a leading authority in applying Jewish religious law to reproductive issues. (Ex. 8 at 15:2 - 16:21.)

5. Rabbi Tendler confirmed that Jewish law would not condone a decision to abort a fetus that had CF, but suggested that Plaintiffs could get married and then reduce their risk of becoming the parents of a child with CF by undergoing IVF and PGD to build their family. (Ex. 8 at 15:11 - 15; 19:10 - 14.)

6. The Grossbaums got married on August 22, 2002. (Ex. 9 at 9:17 - 18; Ex. 8 at 8:22 - 9:2.)

7. From the date of their wedding until after the birth of the infant plaintiff, Rosie Grossbaum, the Grossbaums lived in Brooklyn, New York. (Ex. 9 at 9:22 - 10:14.)

8. Because of their status as CF carriers, in late 2003 or early 2004, when the Grossbaums decided they were ready to start a family, they sought out the Program for IVF, Reproductive Surgery and Infertility at New York University School of Medicine (together with co-defendant New York University Hospitals Center, hereinafter “NYU” or the “NYU Defendants”). (Ex. 9 at 192:5 - 194:6; Ex. 8 at 20:11 - 21:13; Ex. 13 (Chaya Morganstern-Grossbaum’s NYU Medical Records) at CG046.)

9. NYU is located on First Avenue in New York, New York. (Ex. 17 (NYU Semen Collection Record); Ex. 19 (NYU Consent Agreement).)

10. Plaintiffs agreed to undergo in vitro fertilization (“IVF”) treatment at NYU, and then to have cells from the embryos they created through IVF biopsied and sent to defendant Genesis Genetics Institute, LLC (together with its founder and director, individually named defendant Mark R. Hughes, hereinafter “Genesis”) for genetic analysis intended to determine which embryos were affected with CF. (Ex. 9 at 49:4 - 25; Ex. 8 at 21:14 - 16.)

11. Genesis Genetics Institute, LLC is a Michigan limited liability corporation with its sole place of business in Detroit, MI. (Ex. 22 (Complaint And Jury Demand) at ¶ 3.) Mark R. Hughes, its founder and director, has been a Michigan resident since 1998, and has been employed by Genesis Genetics Institute, LLC at its sole place of business in Detroit, Michigan since he founded it in 2003. (Ex. 6 (Declaration Of Mark R. Hughes In Support Of The Genesis Defendants’ Motion For Summary Judgment) at ¶¶ 5, 6.) Genesis specializes in testing embryos of couples who are carriers for genetic diseases in an effort to help those couples reduce their risk of having children affected with those diseases. (Ex. 6 at ¶ 6.)

12. The Grossbaums, upon NYU’s referral, called Genesis’s Michigan laboratory on March 25, 2004 for an approximately one-hour phone conversation with Hughes to review the PGD procedure as part of the informed consent process. (Ex. 8 at 21:14 - 16; Ex. 7 (Pre-Case Phone Review of PGD Informed Consent); Ex. 13 at CG037 (Mar. 22, 2004 email from M. Hughes to NYU stating that “we need [the Grossbaums] to call for their phone consultation” with handwritten note indicating dialing information and the Grossbaums’ appointment time for their telephone consultation with Mark Hughes); Ex. 13 at CG004 (Mar. 25, 2004 email from M. Hughes to F. Hooper at NYU stating that “I have spoken with the [Grossbaums] at length”); Ex. 13 at CG046 (April 29, 2004

letter from NYU's F. Liccardi to Rabbi Jacobwitz stating that the Grossbaums "have already contacted Mark Hughes to set up biopsy testing").)

13. Following the March 25, 2004 discussion, the Grossbaums executed Genesis's informed consent document, which was sent to Genesis for its files. (Ex. 13 at CG093 - CG097 (Preimplantation Genetic Diagnosis Patient Informed Consent).)

14. Pursuant to NYU's instructions, the Grossbaums sent their payment for the PGD testing directly to Genesis at its Michigan facility. (Ex. 28 (Genesis Genetics Institute Paid Invoice); Ex. 29 (May 22, 2004 through January 25, 2005 email chain including Chaya Grossbaum, Genesis's Shannon Wiltse, and NYU's Francis Hooper).)

15. In late June and July of 2004, the Grossbaums underwent IVF with NYU, and PGD with Genesis. (Ex. 13.)

16. Chaya Grossbaum took the fertility medications required as part of the IVF process, which increased the number of mature eggs her body produced that month. (Ex. 13 at CG010 (noting that 33 oocytes were retrieved); Ex. 13 at CG059 (Oocyte Retrieval Operative Report); Ex. 13 at CG069 (recording use of fertility medication Follistim).)

17. Despite Chaya Grossbaum's significantly increased fertility, the Grossbaums chose not to abstain from intercourse during the fertility treatment cycle, even though abstaining, of course, was the only 100% reliable method of assuring that any ensuing pregnancy would develop from an embryo tested by Genesis. (Ex. 13 at CG129 (IVF Semen Collection Record); Ex. 9 at 148:21 - 151:18; Ex.8 at 57:17 - 58:12.)

18. Instead, during their IVF cycle the Grossbaums used an over-the-counter spermicide without a second form of protection, such as a condom, in an attempt to prevent a non-IVF pregnancy. (Ex. 9 at 187:24 - 188:12.)

19. Spermicide, used alone, of course, is a notoriously ineffective contraception method, even where the woman is not also on fertility medications. (Ex. 26.)

20. The July 12, 2004 intercourse was, according to Chaya Grossbaum's testimony, with spermicide, used alone, and the IVF Semen Collection Record reflects that the July 14, 2004 intercourse was with a condom that did not contain spermicide, as this condom was used to collect the sperm to be used to fertilize Chaya Grossbaum's retrieved eggs. (Ex. 9 at 187:24 - 188:12, 191:1-4; Ex. 13 at CG129 (IVF Semen Collection Record dated July 14, 2004).) Condoms, especially used without spermicide, have a significant failure rate. (Ex. 26.)

21. Later on July 14, 2004, an NYU physician retrieved 33 eggs from Chaya Grossbaum's ovaries as part of the IVF process. (Ex. 13 at CG059.) That same day, ten of Chaya Grossbaum's retrieved eggs were successfully fertilized with Menachem Grossbaum's sperm at NYU's facility. (Ex. 13 at CG133.)

22. On July 17, 2004, an NYU embryologist, as requested by the Grossbaums, biopsied their embryos and sent one cell from each embryo to Genesis's Michigan laboratory for analysis. Genesis tested the cells at its Michigan laboratory. (Ex. 13 at CG135 - CG136; Ex. 8 at 56:7 - 13.)

23. On July 19, 2004, Genesis faxed to NYU a document addressing the potential transfer of several embryos. (Ex. 13 at CG064, CG125.)² In this document, Genesis stated "OK for transfer" as to two (2) of the embryos, designated as nos. 8 and 10. *Id.* The document also addressed analysis of the cells

² The parties hotly dispute whether Genesis's full second report was received by NYU. This issue, however, is not relevant to Genesis's Motion For Summary Judgment, which does not include or rely on the disputed second report.

biopsied from other embryos. *Id.* The embryos themselves remained physically located at the NYU Fertility Clinic throughout the IVF process. (Ex. 13 at CG131 - CG134.) On July 19, 2004, only NYU personnel, and through them the Grossbaums, had knowledge of the quality of the embryos. (Ex. 13 at CG134; Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23.)

24. The determination as to the suitability of embryos for in vitro fertilization based upon the results from Genesis was made by NYU reproductive endocrinologist Dr. Frederick Licciardi and NYU embryologist Alexis Adler. (Ex. 9 at 154:5 - 156:23; Ex. 13 at CG134.) Without consulting anyone at Genesis, Licciardi and Adler decided to replace embryo no. 10 with embryo no. 7. The Grossbaums concurred in this decision. (Ex. 13 at CG134; Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23.)

25. That same day, July 19, 2004, embryos no. 7 and 8 were implanted in Chaya Grossbaum. (Ex. 13 at CG134.) Genesis did not learn that NYU had substituted embryo 7 for embryo 10 prior to the embryo transfer. In fact, following its July 19, 2004 report of its results, Genesis had no further involvement with Chaya Grossbaum's IVF cycle or subsequent pregnancy other than making some inquiries to NYU to try to ascertain the cycle's outcome for its records. (Ex. 13; Ex. 9 at 153:12 - 23; 186:19 - 25; Ex. 29.)

26. Genesis has always required that a couple undergoing PGD with it agree that if a pregnancy ensues from IVF, the mother will undergo prenatal testing in the form of chorionic villus sampling ("CVS") or amniocentesis ("amnio"). (Ex. 18 (Deposition of Mark R. Hughes, M.D., Ph.D. dated 2/19/09) at 36:21 - 42:3.) CVS is performed in the 11th or 12th week of pregnancy, and amnio is performed between the 14th and 16th weeks of pregnancy -- here, then, this testing should have been completed by October 25, 2004. (*Id.* at 41:8 - 42:3.)

27. The Grossbaums gave signed agreements that they would undergo amnio or CVS to both the Genesis defendants and NYU. (Ex. 13 at CG090, CG095.) Despite their written agreements to undergo CVS or amnio, however, it was never the intent of the Grossbaums to follow through on this promise; and, in fact, Chaya Grossbaum never underwent either amnio or CVS. (Ex. 9 at 79:21 - 81:23; Ex. 8 at 43:12 - 19.) Both Menachem and Chaya Grossbaum testified that they saw no point in having the agreed-upon testing since they were certain that if the results indicated that the child had CF, they would not have aborted it, and that they would rather remain ignorant of the fetus's CF status during the pregnancy than find it out sooner and spend the rest of the pregnancy anxious about the prospect of parenting a child with CF.³ (Ex. 9 at 80:12 - 81:23; Ex. 8 at 48:21 - 51:19.)

28. On March 25, 2005, Chaya and Menachem Grossbaum, who remained New York residents, became the parents of Rosie Grossbaum.⁴ (Ex. 22 at ¶ 8.) Rosie Grossbaum was born in Denville, New Jersey. *Id.* About two weeks after her birth, Rosie Grossbaum was diagnosed with CF. (Ex. 27 (Deposition of Chaya Grossbaum, Vol II, dated 3/12/09) at 221:5 - 7.)

³ Whether the Grossbaums communicated their refusal to undergo CVS or amnio to Hughes or NYU is one of the most hotly contested fact disputes in this litigation. For summary judgment, however, resolution of this issue is unnecessary -- the Court need only accept the uncontested fact that the Grossbaums chose not to have CVS or amnio testing during the pregnancy.

⁴ Although Fed. R. Civ. P. 5.2 normally requires litigants to redact the names of minor children and birth dates of all litigants, here, where the minor child's full name appears in the caption and Complaint, and the minor child's birth date is not only pled in the Complaint at ¶ 8, but is also potentially relevant to this Court's statute of limitations analysis, Plaintiffs' counsel has agreed to waive Fed. R. Civ. P. 5.2's redaction provisions as to these facts. Other than these consented-to exceptions, we have redacted in accordance with Fed. R. Civ. P. 5.2.

29. At some point after Rosie Grossbaum's birth -- but prior to Plaintiffs' March 23, 2007 filing of this lawsuit -- Plaintiffs moved to New Jersey. (Ex. 9 at 9:22 - 10:14.) Plaintiffs filed suit on March 23, 2007 (Ex. 22.) Genesis filed its Answer on September 20, 2007. (Ex. 23 (Answer On Behalf Of Defendants Genesis Genetics Institute, LLC And Hughes, Only).)

II. THE IVF/PGD PROCESS

30. IVF is a process in which the mother takes fertility medications to encourage her ovaries to produce multiple mature eggs at once. (Ex. 13 at CG081 - CG085, ¶ 1.) These eggs are then harvested from the mother. (Ex. 13 at CG081-CG084, ¶ 5.) Each egg is then fertilized with sperm from the father to create an embryo. (Ex. 13 at CG081-084, ¶ 6.) In typical IVF, one or two of the embryos are implanted into the mother on the fifth day of their existence, the selection of the embryos being dependent upon the extent of their cellular development. (Ex. 13 at CG081-084, ¶ 10.) IVF is typically utilized to overcome fertility problems. (Ex. 13 at CG081-084 (preamble).) If, however, a couple is seeking to avoid a congenital problem, PGD is superimposed upon the IVF process. (Ex. 13 at CG089-092.)

31. Preimplantation genetic diagnosis, as its name implies, involves the diagnosis before implantation of embryos to determine whether the embryo is affected with the disease or condition sought to be prevented, whether it is a carrier of the condition, or whether it is unaffected. (Ex. 13 at CG089-092.) One cell is biopsied from each of the embryos created in the IVF lab, and those individual cells -- one from each embryo -- are then sent to the PGD lab for analysis. (Ex. 13 at CG089-092, ¶ 3.) After the cells are analyzed, their condition is reported to the IVF clinic; and the IVF clinic and the involved would-be parents make a decision

as to which embryos, if any, will be implanted. (Ex. 13 at CG089-092 ¶¶ 4, 5; Ex. 13 at CG134; Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23; Ex. 11 (Deposition Transcript of Dr. Frederick Luccardi, dated 3/11/09) at 62:18 - 63:17.) This decision takes into account both the analysis of the biopsied cells and the quality of the embryos. (Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23.)

32. In early-to-mid 2004, when the events occurred that are the subject of this case, there were approximately eight laboratories in the United States that were doing PGD. (Ex. 1 (Deposition of Dr. Charles Strom, Vol. I, dated 5/4/10) at 112:7-8, 15-16, 18-23; 113:2 - 16.) Only a few of these laboratories, however, were performing PGD analyses in any significant volume. (Ex. 18 at 26:17 - 25.) PGD was then, and is now, a highly sophisticated, rapidly evolving technology. There are thousands of genetic mutations; and it is necessary to devise a separate PGD test for each such mutation, often in an extremely short period of time. *Id.* at 31:14 - 33:17.)

33. There were two primary ways in which labs in the United States did PGD in early-to-mid 2004. (Ex. 13 at CG089-092, ¶ 4.) All but one lab, including Genesis, routinely performed PGD with single cell testing. (Ex. 6 at ¶ 10; Ex. 5 (Expert Report of Kangpu Xu, dated 2/26/10) at 2.) One laboratory, Reproduction Genetics Institute (“RGI”), performed multiplex (or genetic marker) testing. (Ex. 6 at ¶ 10.) Multiplex testing was in its infancy in the United States at that time. *Id.* It involves obtaining one embryonic cell after IVF, and then comparing the cell with cells taken from other family members of the involved couple. (Ex. 2 (Deposition of Mark R. Hughes, dated 5/14/10) at 49:17 - 54:20.) Various other laboratories, including Genesis, were trying to develop this technology in America; but as of the dates in question, the success rate they achieved in trial runs was not sufficiently high for the technique to be used on a regular basis. (*Id.*; Ex. 6 at ¶ 9, 10.)

34. Dr. Kangpu Xu (“Xu”), the retained liability expert for the Genesis defendants, was actively involved in the PGD laboratory at Weill Cornell School of Medicine in New York City at the time the incidents that form the subject matter of this lawsuit took place. (Ex. 5 at 1-2.) Dr. Xu opined that using linkage markers (another term for multiplex testing) was not the standard of care in 2004. (*Id.* at 2.) Indeed, he explained that during the relevant time period, those linkage markers were not necessarily used, even where the risk of misdiagnosis was significantly higher than that faced by the Grossbaums:

Finding informative linkage markers is not trivial task or an overnight procedure. Building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004. During a period from 2001 to 2005, we successfully performed PGD for RB, an autosome disorder with 50% risk without using markers. The reason was not that we were ignorant, but with the limitation that we had because we could not find markers that were informative for the couple. Three healthy singletons were born from 4 different IVF-PGD attempts. **I believe tests conducted by Dr. Hughes were proper, appropriate and within the standard of practice existing at the time for this couple.**

(*Id.* (emphasis added).)

35. The failure rate of single cell PGD was less than five percent (5%) in early-to-mid 2004, although Genesis enjoyed a far smaller failure rate, in the area of two percent (2%) or less. (Ex. 18 at 31:3 - 13.) The main problem with single cell testing was that it was difficult to predict allele drop out (“ADO”), a known complication in PGD. (Ex. 2 at 33:6 - 19; Ex. 5 at 2.) During their telephone conversation with Dr. Hughes, the five percent rate was quoted to the

Grossbaums, and they were otherwise fully informed as to the nature and risks of PGD. (Ex. 9 at 120:15 - 121:12, 171:4 - 172:9; Ex. 8 at 32:14 - 16; Ex. 16 (Deposition of Dr. Kangpu Xu, dated 5/13/10) at 100:12 - 25, 101:13 - 16, 101:23 - 25, 102:1 - 25, 103:1 - 5; Ex. 13 at CG093-CG097, ¶ 5, 6.)

36. The plaintiffs' liability experts, Dr. Charles Strom ("Strom") and Dr. Garry Cutting ("Cutting"), have both testified that the standard of care required that defendants Hughes and Genesis perform genetic marker, or multiplex, testing in the PGD done for the Grossbaums, and that their failure to do so was the likely proximate cause of the infant plaintiff being born with cystic fibrosis. (Ex. 24 (Expert Report of Dr. Garry R. Cutting, dated 9/29/09) at 3; Ex. 25 (Expert Report of Dr. Charles M. Strom, dated 11/12/09) at 2.) Cutting, however, testified at his deposition that Strom miscalculated the increased failure risk associated with the fact that Genesis did not use multiplex testing with the Grossbaums. (Ex. 15 (Deposition of Dr. Garry Cutting, Vol. II, dated 11/8/10) at 283:2 - 7.)

37. At the time in question, only RGI was regularly doing multiplex testing for cystic fibrosis in the United States. (Ex. 1 (Deposition of Dr. Charles Strom, Vol. I, dated 5/4/10) at 122:2 - 23; Ex. 4 (Deposition of Dr. Garry R. Cutting, Vol. I, dated 4/24/10) at 156:3 - 25, 157:1 - 25, 158:1 - 4, 161:10 - 25, 162:1 - 21.) Literature in Europe suggested that this technique was promising, but the average reasonably prudent PGD lab in America was not performing such testing. (Ex. 2 at 47:4 - 49:3.) At his deposition, Hughes explained that the fact that a few papers had been published touting the advantages of multiplex testing did not instantly establish such testing as the new standard for mainstream clinical practice in the United States, given that such results needed to be validated. (Ex. 18 at 47:4 - 48:17.) Indeed, with the exception of RGI, Plaintiffs have not offered any evidence of what the standard practice was at the other U.S. PGD laboratories.

(*Id.* at 48:18 - 49:3; *see generally* Ex. 1, Ex. 3, Ex. 4, Ex. 15 (Deposition of Dr. Garry Cutting, Vol. II, dated 11/8/10).)

III. ADDITIONAL FACTS PERTINENT TO THE DAUBERT MOTION, WHICH, IF GRANTED, WOULD REQUIRE THIS COURT TO GRANT SUMMARY JUDGMENT IN GENESIS'S FAVOR

38. Dr. Charles Strom, plaintiffs' retained liability expert against Defendants Genesis and Hughes, stated in his deposition that as of 2004, there were no more than eight laboratories in the United States that were performing preimplantation genetic diagnosis (PGD): 1) RGI, in Chicago; 2) Reprogenetics, in New Jersey, 3) Genetics and IVF, in Virginia; 4) Cornell Medical Center, in New York City; 5) Genesis Genetics, in Detroit; 6) Shady Grove, in North Carolina; 7) Baylor University; 8) a lab whose name he does not know, in Florida. (Ex. 1 at 112:7 - 8, 15-16, 18-23; 113:2 - 16.)

39. Strom testified that except for Genesis, which he knows from the discovery in this case was not doing multiplex testing in 2004, and RGI, he does not know if any of the other labs mentioned above were doing multiplex testing. (Ex. 1 at 122:2 - 23.)

40. The only lab Strom knows "for sure" that was doing testing with multiplex genetic markers in 2004 was RGI; and he is not specifically aware of any other lab that was using this technology at the time. (Ex. 1 at 84:25, 85:1 - 10.)

41. Strom asserted that in 2004, RGI, which he believed to be doing multiplex testing, was "providing probably over half the services for PGD in the country at the time." (Ex. 1 at 121:7 - 20.) The fact that is undisputed is that Strom made this assertion, not that it is true, nor that the volume any given lab has in any way governs the standard of care.

42. Strom testified that when he was connected with RGI, from 1992 to 2000, he was the person doing PGD for that institution. During that “eight-year span,” he performed “probably a couple of hundred” PGD analyses for cystic fibrosis. (Ex. 1 at 50:21 - 25, 51:1 - 3.)

43. Strom testified that these PGD analyses resulted in “probably thirty births, I would guess. Thirty to forty births.” (Ex. 1 at 51:4 - 9.)

44. Per contra, Genesis has done 582 PGD cycles or tests in the calendar year 2004 alone. (Ex. 2 at 43:10 - 25, 44:1.)

45. Strom testified that he is currently employed by Quest Diagnostics. He started working at Quest in October, 2000. (Ex. 1 at 20:12 - 20.) Strom testified that neither he nor Quest has been engaged in PGD during the time that he has been employed there. (Ex. 1 at 22:18 - 22, 26:3 - 6.)

46. Strom testified that he teaches “everything genetics” at University of California San Diego (“UCSD”), that he “sometimes” touches on PGD in his lectures at UCSD, and that his teaching involving PGD is “probably less than five percent.” (Ex. 1 at 22:23 - 25, 23:1 - 14.) Strom testified that while “some” of his lecturing outside of teaching involves PGD, this percentage is about two to three percent. (Ex. 1 at 23:15 - 25, 24:1 - 18.)

47. Strom testified that he has given about a dozen depositions, but none in PGD or IVF cases, nor has he given a deposition in any case involving cystic fibrosis. (Ex. 1 at 16:24 - 25, 17:1 - 16.) The only wrongful birth case in which Strom has testified involved serum screening, an issue not involved in this case. (Ex. 1 at 17:17 - 25, 18:1 - 3). He has, therefore, never been certified or deemed qualified by a Court to testify as an expert as to issues involving PGD.

48. Strom testified that in formulating his opinions as to the alleged breach of the standard of care by defendants Hughes and Genesis, he does not limit his definition of that term to the United States. (Ex. 1 at 69:23 - 25, 70:1 - 9.)

49. The only materials Strom has reviewed in preparation for formulating his opinions in this case are the records of Genesis, and transcripts of the depositions of Hughes, Dr. Garry Cutting (“Cutting”), and Dr. Kangpu Xu (“Xu”). He has not been provided with the records of NYU, or with transcripts of the depositions of any of the other witnesses in the case, including the adult plaintiffs and the various NYU personnel. (Ex. 1 at 8:12 - 25, 9:1 - 7, 13:20 - 25, 14:1 - 25, 15:1 - 25, 16:1 – 6.) (Ex. 3 at 166:4 - 19.)

50. Strom testified that the standard of care did not require that polar biopsy be done or offered in 2004. (Ex. 3 at 167:8 - 25.)

51. Cutting is a liability expert retained by the plaintiffs to offer opinions primarily against NYU; but he has additionally offered opinions critical of defendants Hughes and Genesis. By way of education, background and training, Cutting is a board certified pediatrician. His fellowship training is in medical genetics, which involves the “care, diagnosis. . . and treatment of patients with a variety of genetic disorders.” This is to be distinguished from PGD, which is concerned with the prevention of such disorders before implantation of embryos in an in vitro fertilization setting. (Ex. 4 at 10:18 - 25, 11:1 - 23.)

52. Cutting is not now involved directly in performing PGD. (Ex. 4 at 117:12 - 25.) Similarly, Cutting was not directly involved in PGD in the year 2004. (Ex. 4 at 118:1 - 11.) In his entire career, Cutting has been directly involved in only two (2) PGD cases, which took place “[p]robably more than 12 months ago, but not more than three years ago.” (Ex. 4 at 117:12 - 25, 118:1 - 25, 119:1 - 7.)

53. At the time of his deposition, Cutting believed that there were two (2) or three (3) labs in the United States doing PGD. (Ex. 4 at 123:4 – 5.) Cutting has never been a member of the PGD International Society or any PGD

group of scientists in the United States, Canada, or elsewhere in the world. (Ex. 4 at 146:18 - 23.)

54. Cutting is aware that RGI was doing multiplex testing for cystic fibrosis in 2004; but he does not know what was being done by Reprogenetics in New Jersey or by Cornell Medical Center in 2004, and he had never heard of Genetics and IVF in Virginia. (Ex. 4 at 156:3 - 25, 157:1 - 25, 158:1 - 4.)

55. Cutting does not know whether in early to mid-2004, the average PGD provider in the United States with reasonable skill and care was using genetic markers for testing for cystic fibrosis in individuals undergoing PGD. (Ex. 4 at 161:10 - 25, 162:1 - 21.)

56. The only materials Cutting has reviewed in preparation for formulating his opinions in this case are the records of Genesis; the records of NYU; various articles; and transcripts of the depositions of Hughes, Dr. Frederick Licciardi ("Licciardi"), and Embryologist Alexis Adler ("Adler"). He has not been provided with transcripts of the depositions of any of the other witnesses in the case, including the adult plaintiffs and various other NYU personnel. (Ex. 4 at 50:2 - 22.)

57. Cutting testified that the standard of care did not require that polar biopsy be done or offered by defendants Genesis or Hughes in 2004. (Ex. 4 at 181:6 - 25; 182:1.)

58. Xu, the retained liability expert for defendants Genesis and Hughes, was actively involved in the PGD laboratory at Weill Cornell School of Medicine in New York City at the time the incidents that form the subject matter of this lawsuit took place; and he has stated that Cornell did not routinely utilize multiplex testing at that time, and that the use of multiplex testing was not required by the standard of care in 2004:

Finding informative linkage markers is not trivial task or an overnight procedure. Building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004. During a period from 2001 to 2005, we successfully performed PGD for RB, an autosome disorder with 50% risk without using markers. The reason was not that we were ignorant, but with the limitation that we had because we could not find markers that were informative for the couple. Three healthy singletons were born from 4 different IVF-PGD attempts. I believe tests conducted by Dr. Hughes were proper, appropriate and within the standard of practice existing at the time for this couple.

(Ex. 5 at 2.) (Emphasis added.)

59. During his entire career in the field of PGD, Hughes has constantly monitored the scientific literature and best practices at the other laboratories that provide PGD as well as stayed active in PGD-related professional organizations and attended PGD-related conferences (often as a speaker, panelist, or other presenter) in an effort to ensure that the PGD services provided by the laboratories he has been associated with, including Genesis, have incorporated all proven technological advances into the services they offer to couples. He has also been a member in good standing of the Preimplantation Genetic Diagnosis International Society and President of the PGD-SIG of the American Society of Reproductive Medicine, the foremost organization in this field. (Ex. 6 at ¶ 8.)

60. Because the PGD field is constantly evolving and changing, scientists are constantly publishing articles describing the latest technology trials. Publication of an article in the scientific literature describing a possible advance in PGD technology or techniques does not dictate that the PGD laboratories will immediately change their standard practices: first, the results provided by the new

technology or technique must be replicated repeatedly, over time; second, evidence must be collected demonstrating that the new technology or technique provides a significant benefit and no harm over the previous methodology; and finally, the technology or technique must be refined and adapted as necessary to be commercially viable. The length of time between publications and clinical implementation of a medical technique often requires several years. (Ex. 6 at ¶ 9.)

61. In 2004, Genesis was not performing multiplex DNA amplification of genomic markers for clinical PGD. Genesis had seen the results published by RGI of Chicago, but had had trouble replicating them in its laboratory. Furthermore, Genesis' error rate without using multiplex markers was significantly lower than the industry average reported error rate. Finally, while Genesis was aware that RGI in Chicago was providing multiplex testing to couples at the time, Genesis agreed with Xu and others that the evidence did not yet support offering multiplex testing as the standard of care. (Ex. 6 at ¶ 10.)

62. At his deposition, Strom identified laboratories that he said were performing PGD in early-to-mid 2004. The laboratories he identified were:

- "RGI in Chicago" (Ex. 1, Strom Dep., 5/4/10, p. 112:7 - 8);
- "Reprogenetics in New Jersey" (Ex. 1 at 112:15 - 16);
- "Genetics and I.V.F. in Virginia" (Ex. 1 at 112:18 - 20);
- "Cornell Medical Center in New York City" (Ex. 1 at 112:21 - 23);
- "Shady Grove" of "North Carolina" (Ex.1 at 113:2 - 16);
- "Baylor" (Ex. 1 at 113:2 - 12); and
- "a lab in Florida that was trying to develop P.G.D." (Ex. 1 at 113:9 - 12).

(Ex. 6 at ¶ 11.)

63. Strom's testimony betrays not only his lack of knowledge regarding the standard of care at United States PGD laboratories in 2004, but also displays that he was not even aware of which laboratories were performing PGD at

that time. For instance, Shady Grove (of Washington, D.C., not North Carolina) was not independently performing PGD in 2004, but instead was sending all of its PGD work to Genesis at that time. (Ex. 6 at ¶ 12.)

64. From Hughes' active participation in the PGD community and interaction with professionals at these institutions, he is familiar with the practices of these laboratories in the 2004 time frame. To the best of his knowledge, in July of 2004, when Genesis performed its study of the Grossbaums' embryos, the only United States laboratory that routinely offered multiplex testing to its patients was RGI of Chicago, Illinois. In particular, from Hughes' previous association with the Prenatal Genetics Center at Baylor, he is aware that Baylor was not routinely providing multiplex testing in early-to-mid 2004. (Ex. 6 at ¶12.)

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